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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: James R. Dasch and M. Gary I. Riley  
Application No.: 10/758,717 Group Art Unit: 1654  
Filed: January 16, 2004 Examiner: Not Assigned  
Confirmation No.: 6559

Title: METHOD OF MODIFYING THE RELEASE PROFILE OF SUSTAINED  
RELEASE COMPOSITIONS

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INFORMATION DISCLOSURE STATEMENT

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Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☐ Copies of the cited references are enclosed.
    - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application Nos. 09/835,001 and 10/400,162, to which priority under 35 U.S.C. 120 is claimed. The earlier applications contain copies of the cited references.
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
    - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

\_\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

\_\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

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Examiner

\_\_\_\_\_  
Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [     ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[     ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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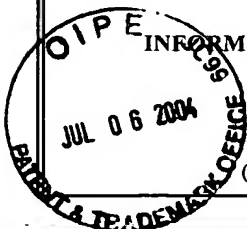
Dated: *July 01, 2004*

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
1733.1068-008APPLICATION NO.  
10/758,717FIRST NAMED INVENTOR  
James R. Dasch, *et al.*FILING DATE  
January 16, 2004EXAMINER  
Not AssignedCONFIRMATION NO.  
6559GROUP  
1654INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

July 1, 2004

(Use several sheets if necessary)



## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	4,746,654	05/24/88	Breliere, <i>et al.</i>
	AB	4,922,007	05/01/90	Kieczkowski, <i>et al.</i>
	AC	5,019,651	05/28/91	Kieczkowski
	AD	5,196,409	03/23/93	Breuer, <i>et al.</i>
	AE	5,312,954	05/17/94	Breuer, <i>et al.</i>
	AF	5,412,141	05/02/95	Nugent
	AG	5,618,563	04/08/97	Berde, <i>et al.</i>
	AH	5,700,485	12/23/97	Berde, <i>et al.</i>
	AI	5,885,973	03/23/99	Papapoulos, <i>et al.</i>
	AJ	6,080,779	06/27/00	Gasper, <i>et al.</i>
	AK	6,117,856	09/12/00	Binderman, <i>et al.</i>
	AA2	6,162,929	12/19/00	Foricher, <i>et al.</i>
	AB2	6,165,513	12/26/00	Dansereau, <i>et al.</i>
	AC2	3,523,906	08/11/70	Vrancken, <i>et al.</i>
	AD2	3,691,090	09/12/72	Kitajima, <i>et al.</i>
	AE2	3,737,337	06/05/73	Schnoring, <i>et al.</i>
	AF2	3,891,570	06/24/75	Fukushima, <i>et al.</i>
	AG2	3,960,757	06/01/76	Morishita, <i>et al.</i>
	AH2	4,327,039	04/27/82	Blum, <i>et al.</i>
	AI2	4,389,330	06/21/83	Tice, <i>et al.</i>
	AJ2	4,705,651	11/10/87	Staibano
	AK2	5,091,400	05/28/91	Gombotz, <i>et al.</i>
	AA3	5,583,122	12/10/96	Benedict, <i>et al.</i>
	AB3	5,654,010	08/05/97	Johnson, <i>et al.</i>
	AC3	5,656,297	08/12/97	Bernstein, <i>et al.</i>
	AD3	5,667,808	09/16/97	Johnson, <i>et al.</i>

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>July 1, 2004</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1733.1068-008	APPLICATION NO. 10/758,717	
	FIRST NAMED INVENTOR James R. Dasch, <i>et al.</i>	FILING DATE January 16, 2004	
	EXAMINER Not Assigned	CONFIRMATION NO. 6559	GROUP 1654

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AE3	5,674,534	10/07/97	Zale, <i>et al.</i>
	AF3	5,711,968	01/27/98	Tracy, <i>et al.</i>
	AG3	5,716,644	02/10/98	Zale, <i>et al.</i>
	AH3	5,922,253	07/13/99	Herbert, <i>et al.</i>
	AI3	5,916,597	06/29/99	Lee, <i>et al.</i>
	AJ3	5,773,477	06/30/98	MacLean, <i>et al.</i>
	AK3	5,861,168	01/19/99	Cooke, <i>et al.</i>
	AA4	6,399,592 B1	06/04/02	Whiteford
	AB4	6,558,702	05/06/03	Dasch, <i>et al.</i>

EXAMINER	DATE CONSIDERED
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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	WO 97/07788	06/03/97	Alkermes Controlled Therapeutics, Inc.		
	AM	EP 709 085 A1	01/05/96	Takeda Chemical Industries, Ltd.		
	AN					
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	Dunn, C.J., <i>et al.</i> , "Demonstration of Novel Anti-Arthritic and Anti-Inflammatory Effects of Diphosphonates," <i>Journal of Pharmacology and Experimental Therapeutics</i> , 266(3):1691-1698 (1993).	
AS	Van Gelder, J. M., <i>et al.</i> , "In Vitro and in Vivo Effects of Tetrakisphosphonates on Bone Resorption, Tumor Osteolysis, Ectopic Calcification, and Macrophages," <i>Journal of Pharmaceutical Sciences</i> , 86(3):283-289 (1997).	
AT	Nugent, R.A., <i>et al.</i> , "Pyrazoline Bisphosphonate Esters as Novel Antiinflammatory and Antiarthritic Agents," <i>J. Med. Chem.</i> , 36:134-139 (1993)	
AU	D'Souza, M.J., <i>et al.</i> , "Macrophage Depletion by Albumin Microencapsulated Clodronate: Attenuation of Cytokine Release in Macrophage-Dependent Glomerulonephritis," <i>Drug Development and Industrial Pharmacy</i> , 25(5):591-596 (1999).	
AV	Nugent, R.A., <i>et al.</i> , "Carbonyl-Containing Bisphosphonate Esters as Novel Antiinflammatory and Antiarthritic Agents," <i>J. Med. Chem.</i> , 37:4449-4454 (1994).	
AW	Hyvönen, P.M., and Kowolik, M.J., "Influence of Dichloromethylene Bisphosphonate on the <i>in vitro</i> Phagocytosis of Hydroxyapatite Particles by Rat Peritoneal Exudate Cells: An Electron Microscopic and Chemiluminescence Study," <i>Annals of the Rheumatic Diseases</i> , 51:203-209 (1992).	
AX	Barbier, A., <i>et al.</i> , "Studies on the Chronic Phase of Adjuvant Arthritis: Effect of SR 41319, A New Diphosphonate," <i>Annals of the Rheumatic Diseases</i> , 45:67-74 (1986).	
AY	Van Rooijen, N., <i>et al.</i> , "Transient Suppression of Macrophage Functions by Liposome-Encapsulated Drugs," <i>Trends in Biotechnology</i> , 15:178-185 (1997).	
AZ	Reginster, J.Y., <i>et al.</i> , "Prevention of Postmenopausal Bone Loss by Tiludronate," <i>The Lancet</i> , pp. 1469-1471, (1989, December 23/30).	
AR2	Bijvoet, O.L.M., <i>et al.</i> , "APD in Paget's Disease of Bone," <i>Arthritis and Rheumatism</i> , 23(10):1193-1204 (1980).	
AS2	Francis, M.D., <i>et al.</i> , "The Effects of Disodium Ethane-1-Hydroxy-1, 1-Diphosphonate on Adjuvant Induced Arthritis in Rats," <i>Calc. Tiss. Res.</i> , 9(2):109-121 (1972).	
AT2	Flora, L., "Comparative Antiinflammatory and Bone Protective Effects of Two Diphosphonates in Adjuvant Arthritis," <i>Arthritis and Rheumatism</i> , 22(4):340-346 (1979).	

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	EXAMINER Not Assigned		CONFIRMATION NO. 6559	GROUP 1654

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AU2	Francis, M.D., <i>et al.</i> , "NE-58095: A Diphosphonate Which Prevents Bone Erosion and Preserves Joint Architecture in Experimental Arthritis," <i>Int. J. Tiss. Reac.</i> , XI(5):239-252 (1989).	
AV2	Daoud, A.S., <i>et al.</i> , "The Effect of Ethane-1-Hydroxy-1,1-Diphosphonate (EHDP) on Necrosis of Atherosclerotic Lesions," <i>Atherosclerosis</i> , 67:41-48 (1987).	
AW2	Camilleri, J.P., <i>et al.</i> , "The Effect of Free and Liposome-Encapsulated Clodronate on the Hepatic Mononuclear Phagocyte System in the Rat," <i>Clin. Exp. Immunol.</i> , 99(2):269-275 (1995).	
AX2	Biewenga, J., <i>et al.</i> , "Macrophage Depletion in the Rat After Intraperitoneal Administration of Liposome-Encapsulated Clodronate: Depletion Kinetics and Accelerated Repopulation of Peritoneal and Omental Macrophages by Administration of Freund's Adjuvant," <i>Cell Tissue Res.</i> , 280(1):189-196 (1995).	
AY2	Van Rooijen, N., <i>et al.</i> , "Depletion and Repopulation of Macrophages in Spleen and Liver of Rat After Intravenous Treatment with Liposome-Encapsulated Dichloromethylene Diphosphonate," <i>Cell Tissue Res.</i> , 260(2):215-222 (1990).	
AZ2	Delemarre, F.G.A., <i>et al.</i> , "Repopulation of Macrophages in Popliteal Lymph Nodes of Mice After Liposome-Mediated Depletion," <i>Journal of Leukocyte Biology</i> , 47(3):251-257 (1990).	
AR3	Storm, T., <i>et al.</i> , "Effect of Intermittent Cyclical Etidronate Therapy on Bone Mass and Fracture Rate in Women with Postmenopausal Osteoporosis," <i>New England Journal of Medicine</i> , 322(18):1265-1271 (1990).	
AS3	Ralston, S.H., <i>et al.</i> , "A Double Blind Placebo-Controlled Trial of Diphosphonate (APD) Therapy in Rheumatoid Arthritis-Preliminary Results," <i>Calcified Tissue</i> , Supplement to Vol. 42, p. A23, Abstract No. 90 (1988).	
AT3	Markusse, H.M., <i>et al.</i> , "Bisphosphonates in Collagen Arthritis," <i>Rheumatology International</i> , 9(6):281-283 (1990).	
AU3	Vyavahare, <i>et al.</i> , "Synergism of Calcium-Ethanehydroxybisphosphonate (CaEHBP) and FeCl <sub>3</sub> : Controlled Release Polymers for Preventing Calcification of Bioprosthetic Aortic Wall," <i>Journal of Controlled Release</i> , 34:97-108, (1995).	
AV3	Weidenauer, U., <i>et al.</i> , "Microencapsulation of hydrophilic drug substances I using biodegradable polyesters. Part 1: Evaluation of different techniques for the encapsulation of Pamidronate di-sodium salt", <i>J. Microencapsulation</i> , 20(4): 509-524 (2003).	

EXAMINER	DATE CONSIDERED
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